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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Graham P. Allaway, et al.
Serial No. : 09/904,356 Examiner: TBD
Filed : July 12, 2001 Group Art Unit: 1648
For : METHODS FOR USING RESONANCE ENERGY
TRANSFER-BASED ASSAY OF HIV-1 ENVELOPE
GLYCOPROTEIN-MEDIATED MEMBRANE FUSION, AND
KITS FOR PRACTICING SAME

1185 Avenue of the Americas
New York, New York 10036
August 14, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

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INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**. Copies of these references are attached hereto as **Exhibits 1-25** respectively.

1. Allan, J., (1997) "Human Immunodeficiency Virus-Related Infections in Animal Model Systems," in AIDS: Biology, Diagnosis, Treatment, and Prevention, fourth edition, De Vita, Jr., et al., eds., Lippincott-Raven Publishers, Philadelphia, pp. 15-25 (**Exhibit 1**)
2. Benet et al., (1990) "Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination," in Goodman and Gilman's The Pharmacological Basis of Therapeutics, Gilman et al., eds., Pergamon Press, New York, pp. 3-32 (**Exhibit 2**)

Applicant : Graham P. Allaway
Serial No. : 09/904,356
Filed : July 12, 2001
Page 2

3. Chams, et al., (1992) "Simple Assay To Screen for Inhibitors of Interaction between the Human Immunodeficiency Virus Envelope Glycoprotein and Its Cellular Receptor, CD4", Antimicrobial Agents and Chemotherapy, 36(2):267-272 **(Exhibit 3)**
4. Crowe, S.M., et al., (1992) "Human immunodeficiency virus-infected monocyte-derived macrophages express surface gp120 and fuse with CD4 lymphoid cells in vitro: a possible mechanism of T lymphocyte depletion in vivo.", Clinical Immunology and Immunopathology, vol. 65, No. 2, pp. 143-151 **(Exhibit 4)**
5. Dimitrov, D.S., et al., (1991) "Initial Stages of HIV-1 Envelope Glycoprotein-Mediated Cell Fusion Monitored by a New Assay Based on Redistribution of Fluorescent Dyes", AIDS Res. & Human Retroviruses, 7(10):799-805 **(Exhibit 5)**
6. Dragic, et al., (1993) "Different Requirements for Membrane Fusion Mediated by the Envelopes of Human Immunodeficiency Virus Types 1 and 2", Journal of Virology, 67(2):2355-2359 **(Exhibit 6)**
7. Ebadi, M., (1998) "The Pharmacokinetic Basis of Therapeutics," in CRC Desk Reference of Clinical Pharmacology, CRC Press LLC, Boca Raton, pp. 1-7 **(Exhibit 7)**
8. Fouchier, et al., (1994) "HIV-1 Macrophage Tropism Is Determined at Multiple Levels of the Viral Replication Cycle", Journal of Clinical Investigation, 94:1806-1814

Applicants : Graham P. Allaway
Serial No. : 09/904,356
Filed : July 12, 2001
Page 3

(Exhibit 8)

9. Graham et al., (1995) "Candidate AIDS Vaccines", New England Journal of Medicine, 333:1331-1339 **(Exhibit 9)**
10. Hirsch et al., (1997) "Antiretroviral Therapy", in AIDS: Biology, Diagnosis, Treatment, and Prevention, fourth edition, De Vita, Jr., et al., eds., Lippincott-Raven Publishers, Philadelphia, pp. 495-508 **(Exhibit 10)**
11. Keller, P.M., et al., (1977) "A Fluorescence Enhancement Assay of Cell Fusion", Journal of Cell Science, 28:167-177 **(Exhibit 11)**
12. Mitsuya, H., et al., (1985) "Protection of T Cells Against Infectivity and Cytopathic Effect of HTLV-III *In Vitro*", in Retroviruses in Human Lymphoma Leukemia, Miwa, et al. Eds., Japan Sci, Soc. Press, Tokyo/VNU Science Press, Utrecht pp.277-288 **(Exhibit 12)**
13. O'Brien et al., (1990) "HIV-1 Tropism for Mononuclear Phagocytes can be Determined by Regions of gp120 Outside of the CD4-binding Domain", Nature 348:69-73 **(Exhibit 13)**
14. Peden, K. et al, (1991) "Changes in Growth Properties on Passage in Tissue Culture of Viruses Derived from Infectious Molecular Clones of HIV-1_{LAI}, HIV-1_{MAL}, and HIV-1_{ELI}" Virology, 185:661-672. **(Exhibit 14)**
15. Rusche et al., (1988) "Antibodies That Inhibit Fusion of Human Immunodeficiency Virus-Infected Cells Bind a 24 Amino Acid Sequence of the Viral Envelope, gp 120" Proc. Nat.

Applicants : Graham P. Allaway
Serial No. : 09/904,356
Filed : July 12, 2001
Page 4

Acad. Science (USA) Vol. 85, pp. 3198-3202 (**Exhibit 15**)

16. Saag, M., (1997) "Clinical Spectrum of Human Immunodeficiency Virus Diseases", in AIDS: Biology, Diagnosis, Treatment and Prevention, DeVita et al., eds., Lippincott-Raven Publishers, Philadelphia, pp. 203-213 (**Exhibit 16**)
17. Sandstrom, E.G. and Kaplan, J.C., (1987) "Antiviral Therapy in AIDS: Clinical Pharmacological Properties and Therapeutic Experience to Date" *Drugs* 34:372-390 (**Exhibit 17**)
18. Schmidtmayerova, H., et al., (1993) "Characterization of HIV1-PAR a macrophage-tropic strain: cell tropism, virus/cell entry and nucleotide sequence of the envelope glycoprotein.", *Research in Virology*. vol. 144, No. 1, pp. 21-26 (**Exhibit 18**)
19. Sinangil, F. et al, (1988) "Quantitative Measurement of Fusion Between Human Immunodeficiency Virus and Cultured Cells Using Membrane Fluorescence Dequenching" *FEBS Letters* 239:88-92 (**Exhibit 19**)
20. Stein et al., (1993) "Immune-Based Therapeutics: Scientific Rationale and the Promising Approaches to the Treatment of the Human Immunodeficiency Virus-Infected Individual," *Clinical Infectious Diseases* 17:749-771 (**Exhibit 20**)
21. Szabo, G. et al, (1992) "CD4 Changes Conformation Upon Ligand Binding" *J. Immunol.* 149:3596-3604 (**Exhibit 21**)

Applicants : Graham P. Allaway
Serial No. : 09/904,356
Filed : July 12, 2001
Page 5

22. Szabo, G. et al, (1993) "Specific Disengagement of Cell-Bound Anti-LAM-1(Anti-L-Selectin) Antibodies by Aurintricarboxylic Acid" Molecular Immunology, Vol. 30 No. 18:1689-94 **(Exhibit 22)**
23. Wanda, P.E., and Smith, J.D., (1983) "A General Method for Heterokaryon Detection Using Resonance Energy Transfer and a Fluorescence-activated Cell Sorter", Journal of Histochemistry & Cytochemistry 30(12):1297-1300 **(Exhibit 23)**
24. Yarchoan et al., (1988) "Clinical Aspects of Infection with AIDS Retrovirus: Acute HIV Infection, Persistent Generalized Lymphadenopathy, and AIDS-Related Complex", in AIDS: Etiology, Diagnosis, Treatment and Prevention, DeVita et al., eds., Lippincott-Raven Publishers, Philadelphia, pp. 107-109 **(Exhibit 24)**
25. International Publication No. WO 95/16789 published June 22, 1995, "Methods for Using Resonance Energy Transfer-Based Assay of HIV-1 Envelope Glycoprotein-Mediated Membrane Fusion, and Kits for Practicing Same" **(Exhibit 25)**

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

Applicants : Graham P. Allaway
Serial No. : 09/904,356
Filed : July 12, 2001
Page 6

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement since this filing is being made prior to the mailing of a first Office Action on the merits of this case under 37 C.F.R. § 1.97(b)(3). However should any fee be due, authorization is hereby given to charge the required amount to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
<i>Mark A. Farley</i>	<i>8-14-02</i>
Mark A. Farley Reg. No. 33,170 John P. White Reg. No. 28,678	Date